UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JUDGE COTE

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MIRIAM PASCAL,

Plaintiff,

08 CV 2040

Case No:

-against-

COMPLAINT

ELI LILLY & CO.,

Plaintiff herein demands a jury trial.

Defendant.

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Plaintiff, by her attorneys, PODLOFSKY HILL ORANGE & MODZELEWSKI, LLP, complaining of the defendant, allege upon information and belief as follows:

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JURISDICTION AND VENUE

1. This action is brought pursuant to the laws of the State of New York.

2. This court has diversity jurisdiction pursuant to 28 U.S.C. §1332(a).

3. Venue is based pursuant to 28 U.S.C. §1391(a)(2).

PARTIES

4. Defendant is a business entity existing under the laws of the State of Indiana, with its principal place of business located at the Lilly Corporate Center, City of Indianapolis, State of Indiana. Upon information and belief, at all relevant times, defendant was and is duly authorized to do business, and regularly does and/or solicits business in the State of New York, and derives substantial revenue from goods used or consumed in the State of New York.

5. Plaintiff MIRIAM PASCAL, is a citizen of the United States and resident of the State of New York, and resides at 65 Remsen Avenue, Town of Monsey, County of Rockland, State of New York.

FACTUAL ALLEGATIONS

6. Zyprexa is a medication designed, engineered, produced, manufactured, marketed, distributed and promoted by the defendant particularly for use in patients suffering from schizophrenia and bipolar disorder.

7. Contrary to the representations and promises make by defendant as to the effectiveness, safety and reliability of Zyprexa, such products were in fact defective and caused deleterious side effects, including but not limited to causing adult onset diabetes, and were not suitable for use in patients.

8. On or about July 1, 1998, plaintiff MIRIAM PASCAL, then only nine years old (plaintiff's date of birth is July 6, 1988), was prescribed Zyprexa. Shortly thereafter, she contracted serious personal injuries, including adult onset diabetes and lifetime insulin dependence,

9. MIRIAM PASCAL's aforementioned symptomology was proximately caused by the Zyprexa which was administered to her.

10. Defendant designed, manufactured, marketed, sold and distributed Zyprexa to hospitals, physicians, the public at large, patients generally, including the plaintiff herein; failed to disclose that Zyprexa was defective and would cause, inter alia, ailments including diabetes, and otherwise fail when exposed to normal conditions, and even after failures had been reported to them, defendant continued to represent to its physician-customers, patient-customers and others, including plaintiff herein, that Zyprexa was an acceptable medication for patient use; and impliedly warranted that the Zyprexa medication was of merchantable quality, fit for the ordinary purpose of such materials, and suitable for the particular purposes for which they were intended.

11. Zyprexa medications have and had a higher failure rate and incidence of causing the foregoing symptomology than similar medications used and prescribed in the marketplace to treat bipolar disorder and schizophrenia.

12. The Zyprexa medication administered to MIRIAM PASCAL was contained, developed, designed, manufactured, distributed, promoted, sold and marketed by defendant.

13. Defendant knew or should have known but failed to disclose that Zyprexa would cause the foregoing symptomology in patients and otherwise fail when used in ordinary application.

14. The defects in Zyprexa are latent and self-concealing. Accordingly, all applicable statutes of limitation have been tolled.

AS AND FOR A FIRST CAUSE OF ACTION

15. Plaintiff realleges and incorporates herein each and every allegation contained in the complaint as if fully set forth herein.

16. Defendants have been at all pertinent times in the business of designing, manufacturing, testing, inspecting, marketing, distributing and/or selling Zyprexa which was prescribed to MIRIAM PASCAL.

17. By producing, selling, marketing and/or introducing Zyprexa products into the stream of commerce, defendant represented that it was safe and suitable for their foreseeable use.

18. Zyprexa products were expected to and did reach consumers, including plaintiff herein, without substantial change in the condition in which they were designed, produced, manufactured, sold, distributed and/or marketed by the defendant, and in the condition which defendant intended them to reach such consumers.

19. Zyprexa products were in fact defective and unreasonably dangerous in that, among other things, defendant failed to give instructions and/or gave inadequate or improper instructions or warnings covering Zyprexa; failed to advise that Zyprexa products were inherently defective and would cause damages to plaintiff with the foreseeable use of the product; and failed to adequately engineer, design and test Zyprexa to assure its safety for

administration in human subjects.

20. Plaintiff MIRIAM PASCAL used Zyprexa in a foreseeable manner and for the purposes and in a manner normally intended.

21. The defects in Zyprexa were a substantial factor in causing damages to the plaintiff herein.

22. Plaintiff MIRIAM PASCAL could not by the exercise of reasonable care have avoided the damages or discovered the defects herein mentioned and/or perceived their danger.

23. By reason of the foregoing, defendant is strictly liable to plaintiff.

AS AND FOR A SECOND CAUSE OF ACTION

24. Plaintiff realleges and incorporates herein each and every allegation contained in the complaint as if fully set forth herein at length.

25. Defendant owed a duty to plaintiff to exercise the ordinary care and diligence that would have been exercised by a reasonable and prudent designer, manufacturer, producer, distributor, marketer and seller under the dame or similar circumstances.

26. Defendant violated the duty they owed to the plaintiff to exercise the ordinary care and diligence that would have been exercised by a reasonable and prudent designer, manufacturer, producer, distributor, marketer and seller under the same or similar circumstances.

27. Defendant violated the duty they owed to plaintiff to exercise the ordinary care and diligence that would have been exercised by a reasonable and prudent designer, manufacturer, producer, distributor, marketer and seller under the same or similar circumstances.

28. Defendant was negligent in that they developed, marketed, distributed and sold Zyprexa products; failed to adequately inspect or test Zyprexa before introducing it into the marketplace; failed to give warnings or disclosures regarding the limitations of use of Zyprexa; represented that Zyprexa would be suitable for administration to humans, generally, and sufferers

of bipolar disorder and schizophrenia, such as plaintiff herein, specifically; and recommended or specified Zyprexa for use in treating bipolar disorder and schizophrenia, such as the plaintiff herein.

29. Defendant's actions also constitute gross negligence. Such actions were make with knowing disregard for or reckless indifference to the rights of plaintiff, and the reliance of plaintiff on defendant's reputation for designing, manufacturing, distributing and selling superior quality medical products and medication.

30. By reason of defendant's aforesaid negligence, plaintiff sustained serious personal injuries and other damages, and defendant is therefore liable to plaintiff.

AS AND FOR A THIRD CAUSE OF ACTION

31. Plaintiff realleges and incorporates herein each and every allegation contained in the complaint as if fully set forth herein.

32. Defendant, as the designer, manufacturer, distributor, seller and/or marketer of Zyprexa products impliedly warranted that they were safe, merchantable and fit for the ordinary purposes for which they were used.

33. In fact, said warranties were false in that Zyprexa products were and are not safe and not fit for the use intended, and were and are not of merchantable quality.

34. Defendant breached this implied warranty because Zyprexa products are not and never have been safe, merchantable and/or reasonable for ordinary use, but instead are defective.

35. Plaintiff used Zyprexa products for their intended use and/or in a reasonably foreseeable manner.

36. Accordingly, defendant is liable to plaintiff.

37. By reason of the foregoing, as well as plaintiff's reliance on defendant's reputation for designing, manufacturing, marketing, selling and distributing superior products, plaintiff has

sustained serious personal and other injuries, including but not limited to adult onset diabetes and lifelong dependence on insulin.

AS AND FOR A FOURTH CAUSE OF ACTION

38. Plaintiff realleges and incorporates herein each and every allegation contained in the complaint as if fully set forth herein.

39. Defendant, as the designer, manufacturer, distributor, marketer and/or seller of Zyprexa, impliedly warranted that Zyprexa was fit or the particular purposes for which it was used.

40. Defendant, at the time they designed, sold, manufactured, marketed and/or distributed Zyprexa and its systems, knew or had reason to know the purpose for which it would be used by patients such as the plaintiff herein.

41. Defendant, because of its superior knowledge and skill, knew or had reason to know that consumers, including plaintiff, would justifiably rely on defendant's knowledge and skill in electing to take Zyprexa.

42. Plaintiff relied on defendant's knowledge and skill in electing to take Zyprexa.

43. Defendant, by designing, manufacturing, creating, distributing, marketing and selling a product that causes the aforementioned symptomology, created, designed, manufactured, distributed, marketed and sold a product with a concealed hazard which was inherently dangerous.

44. Defendant breached the implied warranty of fitness for particular purpose by designing, manufacturing, distributing and selling Zyprexa products which were not fit for their particular purpose.

45. By reason of the foregoing, defendant is liable to plaintiff.

46. As a result of the negligent, intentional, and otherwise illegal conduct of the

defendant as aforesaid, as in relying on the foregoing representations, and defendant's reputation in the medical products community as designers, manufacturers, distributors and sellers of superior quality products, the plaintiff was caused to suffer substantial personal and other injuries.

AS AND FOR A FIFTH CAUSE OF ACTION

47. Plaintiff realleges and incorporates herein each and every allegation contained in the complaint as if fully set forth herein.

48. Defendant made assertions and/or promises of fact relating to Zyprexa to the government, public and psychiatric community including the plaintiff, including but not limited to assertions and/or promises that Zyprexa was fit and safe for use in patients, and that Zyprexa was a superior material for use in patients with bipolar disorder and/or schizophrenia.

49. Defendant intended through its assertions to induce patients with bipolar disorder and/or schizophrenia, including the plaintiff herein, to elect to take Zyprexa products designed, manufactured, and distributed by defendant administered to her.

50. These assertions were express warranties that were relied upon by the plaintiff in choosing to take Zyprexa.

51. Defendant breached these warranties by offering for sale Zyprexa products that did not conform to defendant's assertions and/or promises.

52. By reason of the foregoing, defendant is liable to plaintiff.

53. As a result of the negligent, intentional and otherwise illegal conduct of the defendants as aforesaid, and in relying on the foregoing representations, and defendant's reputation in the medical products community as designers, manufacturers, distributors and sellers or superior quality products, the plaintiff herein was damaged.

AS AND FOR A SIXTH CAUSE OF ACTION

54. Plaintiff realleges and incorporates herein each and every allegation contained in the complaint as if fully set forth herein.

55. Defendant, as manufacturer, distributor, designer, marketer and seller of Zyprexa, designed and promoted for use in the human body, was required by Federal Law and certain rules and regulations of the United States Food and Drug Administration ("FDA") to file accurate pre-market approval reports and other product safety information with the FDA; establish and maintain procedures for receiving, reviewing and evaluating complaints concerning Zyprexa in accordance with the Code of Federal Regulations; analyze all sources of quality data to identify trends of quality problems in accordance with the Code of Federal Regulations; maintain adequate device master records that include packaging and labeling specifications, including the methods and processes used, in accordance with the Code of Federal Regulations; and, document training to ensure that all personnel are trained to adequately perform their assigned responsibilities in accordance without he Code of Federal Regulations.

56. As a manufacturer, distributor, designer, marketer and seller of a product for implantation in the human body, defendant was required by Federal law and FDA rules and regulations to conduct substantial tests on its product, namely, Zyprexa, prior to the sale and distribution of these devices for ultimate implantation in the patients' bodies.

57. Defendant failed to comply with the foregoing Federal laws and regulations.

58. As a result of the defendant's failure to properly comply with the aforesaid statutory and regulatory requirements governing the marketing, sale, manufacture, testing and distribution of Zyprexa, the defendant was "negligent per se" under New York law.

59. The defendant's presumptive negligence in the manufacture, sale, testing, and distribution of Zyprexa was a substantial factor in causing the aforesaid damages sustained by plaintiff.

60. Accordingly, defendant is liable to plaintiff for the aforesaid damages.

PRAYER FOR RELIEF

WHEREFORE, plaintiff demands judgment as follows:

a) awarding Plaintiff compensatory damages in amounts to be determined at trial, in an amount not less than $10,000,000.00, together with attorneys' fees, interest and costs; and

b) such other and further relief as this Court deems just and proper.

Dated: Great Neck, New York
February 25, 2008

Yours, etc.,

PODLOFSKY HILL ORANGE
& MODZELEWSKI, LLP
Attorneys for Plaintiff

By: _____
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